

**OPTN/UNOS Liver and Intestinal Transplantation Committee
Meeting Summary
August 6, 2014
Conference Call**

**David Mulligan, MD, Chair
Ryutaro Hirose, MD, Vice Chair**

Discussions of the full committee on August 6, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting Summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>

Committee Projects

1. Adding serum sodium to the MELD score (MELD-Na)

The Model for End-stage Liver Disease (MELD) score was implemented in 2002 to reduce death on the liver waiting list, and is assigned to candidates age 12 and older. While the MELD score has been well accepted and proven to achieve this goal, it has not been modified since implementation. The MELD Score and serum sodium (Na) concentration are important predictors of survival among candidates for liver transplantation.

The proposal to add serum sodium to the MELD score calculation was circulated for public comment from March through June of 2013, forwarded to the Board for consideration at the June 23 and 24, 2014 meeting and ultimately approved with an amendment. Upon implementation approximately 34% of candidates will have a different MELD score. Approximately 14% will move to a higher recertification category. The Committee reviewed three potential options for handling anticipated downgrades on implementation day during the last Committee meeting (assuming that laboratory values have not already expired at the time of MELD-Na implementation):

1. Use the recertification schedule applicable to the patient's MELD score, pair MELD recertification date at the time of implementation with the new MELD-Na value
2. Use the recertification schedule applicable to new MELD-Na score, downgrade to previous lower MELD score if insufficient time remaining
3. Use the recertification schedule applicable to new MELD-Na score, if due to expire soon (TBD), reset due date to some "grace period" TBD

The Committee had suggested a 4th option:

4. All candidates would be converted to a new MELD-Na score upon implementation, and the recertification date would be based upon the schedule for the new score as though the date of implementation was the date the labs were entered.

The Committee had agreed at that time that this was the preferred choice and IT staff confirmed that this would not be difficult to implement. Upon further discussion with the Director of Policy, IT and DEQ staff it was determined that this approach would in essence, allow members to a one-time policy violation for the day of implementation and

was therefore not a viable option. The Committee reconsidered Option 3 which would allow a “grace period” before downgrading a candidate to their lower previous MELD in the event that their score expired upon implementation. This option would require a change to the policy language; a transition clause would need to be written in and approved at minimum by the Executive Committee, and potentially by the Board. The Committee agreed the appropriate grace period to be 7 days, consistent across all recertification schedules.

The Committee plans to review and approve this transition language at the upcoming in person meeting on September 17, 2014 in Chicago.

2. Redesigning Liver Distribution

A concept paper introducing the novel idea of Redistricting for liver distribution was released on June 16, 2014, with an accompanying questionnaire seeking community feedback on the concepts described. A total of 694 responses were received; these were considered by the Redesigning Liver Distribution Steering Committee in developing the agenda for a Public Forum to be held in Rosemont, Illinois on September 16, 2014. The intent of the Forum is to further the conversation about broader sharing and to discuss concepts intended to increase equity in access to liver transplantation.

The Committee reviewed and approved the final agenda for the Public Forum on Redesigning Liver Distribution, which was approved by the Steering Committee earlier in the week. The agenda will subsequently be posted online for interested parties to access along with a reminder to register and attend.

3. National Liver Review Board

A proposal for a National Review Board (NRB) was circulated in 2004 but was not well supported. The main concerns received in public comment were that: a NRB was premature, the current Regional Review Board (RRB) system works well, a NRB would take away the ability to work out discrepancies locally, a national process may lengthen review time, and the need for more standardized guidelines for use by the NRB. The proposal was deferred until standardized guidelines for MELD/PELD Exception scores could be refined. The Committee since developed the MESSAGE papers in 2006, and two additional guidance documents in June 2012, detailing evidence-based criteria for MELD/PELD exceptions for specific diagnoses.

In June 2014, the Board reviewed the proposed 2014 construct of a NRB concept, which was based on the 2004 model. The Board was pleased and urged the Committee to develop a proposal for consideration. Committee members agreed that the details of the construct, implementation and transition will need to be further discussed in the development of a proposal.

Review of Public Comment Proposals

4. Proposal to Cap the Hepatocellular Carcinoma (HCC) Exception Score at 34

The HCC Subcommittee reconvened on August 4, 2014 to further consider the feedback received in public comment. There was little controversy over this proposal, although there were suggestions that the cap should be lower than 34. The Subcommittee addressed the suggestions, but recommended that this proposal be forwarded to the Board unchanged. The Committee will consider the Subcommittee’s recommendations and formally vote on whether to forward this proposal for Board consideration at the September 17, 2014 in-person meeting.

5. Proposal to Delay HCC Exception Score Assignment

The Delay HCC Score Assignment Proposal received more critical feedback; however the Subcommittee felt that the lack of support was due to a misunderstanding of the data presented in support of the proposal. Each of the HCC proposals was aimed to address two different populations: the first is targeted for those areas of the country that transplant at very high MELD scores and the second is targeted for those areas of the country that transplant at lower MELD scores. Each policy will only impact one of the two areas, not both. The Subcommittee recommended the proposal should be forwarded to the Board unchanged. The Committee will consider the Subcommittee's recommendations and formally vote on whether to forward this proposal for Board consideration at the September 17, 2014 in-person meeting.

6. Proposed Membership and Personnel Requirements for Intestinal Transplant Programs

The Intestinal Subcommittee has met several times to address the feedback received in public comment. Substantial modifications have been made to the proposed policy that will require another cycle of public comment. The Subcommittee aims to have the new proposal ready for the Committee's review at the September 17, 2014 in-person meeting.

Other Significant Items

7. A Committee member presented the Pediatric Committee's proposed policy to automatically maintain pediatric classification for liver candidates registered prior to the 18th birthday. The proposal aims to promote consistency with other organ policies, educate the community, promote more efficient use of the Regional Review Boards and guarantee consistent outcomes for this small population of candidates.

When this concept was previously presented to the Committee, members had suggested an age cap, i.e., an age after which the pediatric preference would expire, to prevent inappropriate (?) listing practices. The Pediatric Committee considered this suggestion but ultimately was not in favor of a cap based on the lack of data to support an age at which it would be appropriate to cap, inconsistency with other organ policies, and stressed that adequate and appropriate listing practices are necessary and expected. The Committee unanimously voted in support of the Pediatric proposal.

8. The Committee reviewed a work plan outline for the remainder of the calendar year that detailed major events, meetings and what goals and milestones the Committee aims to achieve through December. Additionally the Committee reviewed the changes to the policy development calendar recently approved by the Executive Committee.

Upcoming Meetings

- The next in-person meeting is scheduled for September 17, 2014 in Rosemont, Illinois.
- An additional Committee call will be scheduled in the interim to review the final data analyses on the Redesigning Liver Distribution concept document questionnaire.